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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,856	03/01/2002	Thomas W. Self	6648-PA01	5897
27111	7590	10/04/2004	EXAMINER	
GORDON & REES LLP 101 WEST BROADWAY SUITE 1600 SAN DIEGO, CA 92101			YANG, NELSON C	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,856

Applicant(s)

SELF ET AL.

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/03 6/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

- I. Claim 24, drawn to the machine was mislabeled as claim 22. For the purposes of examination, the claim has been referred to as claim 24.
1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-23, drawn to an assay kit, classified in class 436, subclass 518.
 - II. Claim 24, drawn to a machine for automation of performance of a stool based assay, classified in class 436, subclass 45.
2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The invention of group I requires antigens attached to a matrix, while the invention of group II requires a centrifuge for the separation of solids.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation on September 24, 2004, a provisional election was made with traverse to prosecute the invention of group I, claims 1-23. Affirmation of this election must be made by applicant in replying to this Office action. Claim 24 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

Art Unit: 1641

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

II. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Frank et al [US 5,945,294].

7. With respect to claims 1, 2, 4, 10, 11, 13, Frank et al teach the use of antigens as capture molecules by being immobilized on a substrate such as a microtiter dish well or dipstick, such that antigen:IgE complex formation is possible (column 12, lines 5-11).

The detection of the anti-food antibody has not been given any patentable weight as the limitation refers to a method step, and therefore would not have any patentable weight in a product claim.

8. With respect to claims 3, 5, 12, 14, Frank et al teach a kit comprising multiple food antigens where the antigens are immobilized to a substrate (column 14, line 65 – column 15, line 18).

Art Unit: 1641

9. Claims 6-9, 19-20, and 22-23 recite limitations that refer to method steps which have no patentable weight in a product claim. Since the claims do not recite any structural limitations or indicate any physical elements that would be required to perform these method steps, the claims have not been given any patentable weight.

10. With respect to claims 15-18, Frank et al teach that the substrate material can comprise gels and latex (column 11, line 1-3) and that suitable shapes for the substrate material include wells (column 11, lines 4-6).

11. With respect to claim 21, Frank et al teach that the antigen may be placed in microtiter wells (column 11, lines 4-6). Although Frank et al do not teach that the well walls act as barriers, the walls of the well nevertheless would act as barriers to prevent cross contamination, and therefore would read upon the barriers recited in claim 21.

12. Claims 1, 2, 4, 6-11, 13, 15-23, rejected under 35 U.S.C. 102(e) as being anticipated by Colpitts et al [US 6,552,164].

With respect to claims 1, 2, 4, 10, 11, 13, Colpitts et al teach assay kits for determining the presence of anti-multimeric polypeptide complex antibody in a test sample (column 7, lines 10-13). The test kit can comprise a container with tools useful for collecting test samples, such as stool samples (column 7, lines 15-17). The polypeptide can be attached to a solid phase (column 7, lines 25-26).

13. Claims 6-9, 19-20, and 22-23 recite limitations that refer to method steps which have no patentable weight in a product claim. Since the claims do not recite any structural limitations or indicate any physical elements that would be required to perform these method steps, the claims have not been given any patentable weight.

Art Unit: 1641

14. With respect to claims 15, 16, Colpitts et al teach that the solid phase can be a gel structure in the hydrated state, such as nitrocellulose and nylon (column 23, lines 57-60).
15. With respect to claim 18, the solid phase may be latex particles (column 23, line 20).
16. With respect to claims 17, 21, Colpitts et al teach that the antigen may be placed in microtiter wells (column 23, lines 48-50). Although Colpitts et al do not teach that the well walls act as barriers, the walls of the well nevertheless would act as barriers to prevent cross contamination, and therefore would read upon the barriers recited in claim 21.

Conclusion

III. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/090,856

Page 6

Art Unit: 1641

Nelson Yang
Patent Examiner
Art Unit 1641

B. Nguyen
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PRIMARY EXAMINER
9/30/04